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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,339	08/03/2000	Carl T Wittwer	7475-66667	9681
49437	7590	03/23/2005	EXAMINER	
ROCHE 11 SOUTH MERIDAN STREET INDIANAPOLIS, IN 46204			BEISNER, WILLIAM H	
			ART UNIT	PAPER NUMBER
			1744	
DATE MAILED: 03/23/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/631,339

Applicant(s)

WITTWER ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/14/2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/14/2004 has been entered.

Information Disclosure Statement

2. The information disclosure statement filed 1/14/2005 has been considered and made of record.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 5-9 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by von Behrens (US 3,914,985).

With respect to claim 1, the reference of von Behrens discloses a container (12) for holding a fluidic biological sample that includes a receiving portion (12a) and a reaction portion

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(12b). A liquid sample positioned within the receiving portion (12a) is capable of flowing into reaction portion (12b). As shown in Figure 1, the receiving portion (12a) has a volume greater than the reaction portion (12b). The reaction volume is not greater than 1ml or 10,000microliters (See column 4, lines 26-35). With respect to the recited thermal conductivity of the reaction portion, the reference of von Behrens discloses that the reaction portion (12b) is made of glass (See column 4, line 33) which is a material disclosed by the instant specification as a material with the claimed thermal conductivity (See page 53 of the instant specification). The reference of von Behrens discloses that the end of the reaction portion (12b) can be permanently sealed (See column 5, lines 57-67, and Figure 6).

With respect to claims 2 and 3, receiver portion (12a) is made of a plastic material and is funnel-shaped (See column 5, lines 33-47, and Figure 1).

With respect to claim 5, the reaction volume is not greater than 10microliters (See column 4, lines 26-35).

With respect to claim 6, the glass capillary is transparent (See column 4, line 34).

With respect to claim 7, the reaction portion (12b) is a capillary tube having a first sealed end (See column 4, lines 26-35; column 5, lines 57-67; and Figure 6).

With respect to claims 8 and 9, the reaction volume is not greater than 1ml and is between about 0.01microliter to about 100microliter (See column 4, lines 29-32).

With respect to claims 14 and 15, the reaction portion has a v:sa ratio of less than 1mm or 0.25 mm (See column 4, lines 26-35).

With respect to claim 16, the glass capillary is inherently optically transmissible for light of the claimed wavelength.

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5. Claims 1-4, 6-9 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerarde (US 3,518,804).

With respect to claim 1, the reference of Gerarde discloses a container (10) for holding a fluidic biological sample that includes a receiving portion (12) and a reaction portion (14). A liquid sample positioned within the receiving portion (12) is capable of flowing into reaction portion (14). As shown in Figure 1, the receiving portion (12) has a volume greater than the reaction portion (14). The reaction volume is not greater than 1ml or 10,000microliters (See column 5, lines 41-44). With respect to the recited thermal conductivity of the reaction portion, the reference of Gerarde discloses that the reaction portion (14) is made of glass (See column 4, lines 4-6) which is a material disclosed by the instant specification as a material with the claimed thermal conductivity (See page 53 of the instant specification). The reference of Gerarde discloses that the end of the reaction portion (14) can be sealed (See column 4, lines 48-54, and Figure 3).

With respect to claim 2, receiver portion (12) is made of a plastic material (See column 3, lines 1-10).

With respect to claim 3, the receiver portion (12) is funnel-shaped (See Figure 1).

With respect to claims 4, 17 and 18, the reference discloses the use of plug (24) for sealing receiving portion (12).

With respect to claim 6, the glass capillary is transparent (See column 4, line 4).

With respect to claim 7, the reaction portion (14) is a capillary tube having a first sealed end (See column 4, lines 48-54, and Figure 3).

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With respect to claims 8 and 9, the reaction volume is not greater than 1ml and is between about 0.01microliter to about 100microliter (See column 5, lines 41-44).

With respect to claim 16, the glass capillary is inherently optically transmissible for light of the claimed wavelength.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over von Behrens (US 3,914,985).

The reference of von Behrens has been discussed above.

With respect to claim 10, while the reference of von Behrens is silent with respect to the specific inner and outer diameters of the capillary tube employed, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum capillary dimensions based merely on the intended volumes of samples to be manipulated within the reaction volume.

With respect to claim 11, the specifics of the interface between the funnel shaped upper portion (12a) and lower portion (12b) would have been well within the purview of one having ordinary skill in the art while maintaining a fluid seal between the separate elements (See column 5, lines 33-47).

10. Claims 4, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over von Behrens (US 3,914,985) in view of Gerarde (US 3,518,804).

The reference of von Behrens has been discussed above.

Claims 4, 17 and 18 differ by reciting that the device includes a plug for the receiving portion (12a) of the device.

The reference of Gerarde discloses that it is known in the art to seal the reservoir end of a micropipette device (10) with a plug (24).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to seal the open end of the upper portion (12a) of the device of von Behrens with a plug device as suggested by the reference of Gerarde for the known and expected result of providing an art recognized means for sealing the contents of the pipette device with respect to the atmosphere for protection and/or stabilization.

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over von Behrens (US 3,914,985) in view of Hawes (US 3,556,659).

The reference of von Behrens has been discussed above.

While the reference of von Behrens disclose that the end of the capillary (12b) can be sealed, the reference does not disclose that the end is a "flat tip".

The reference of Hawes discloses that it is conventional in the art to seal the open end of a capillary tube so as to provide a "flat tip" (See Figure 2a and column 5, lines 23-30).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to seal the end of the capillary tube of the primary reference as a "flat tip" for the known and expected result of providing an art recognized means for interfacing the end of the capillary tube with optical interrogation devices.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-12 and 14-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-27 and 34-39 of copending Application No. 10/914,648. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim language of instant claims 1-12 and 14-18 encompass the claim limitations set forth in claims 19-27 and 34-39 of copending application 10/914,648. As a result, claims 19-27 and 34-39 of copending application 10/914,648 anticipate the instant claims. Also any minor differences between the specific claim language would have been obvious to one of ordinary skill in the art when presented with the disclosure of claims 19-27 and 34-39 of copending application 10/914,648.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

14. Applicant's arguments and associated amendments to the claims, see pages 5-9, filed 10/26/2004 and amendments filed 1/14/2004, with respect to the rejection(s) of claim(s) 1-12 and 14-18 under 35 USC 102 and 103 have been fully considered and are persuasive. Therefore, the

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rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the references of von Behrens (US 3,914,985) and Gerarde (US 3,518,804).

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The reference of Gerarde (US 3,045,494) is cited as a prior art reference that pertains to a microcapillary device that does not include a seal capillary end.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner
Primary Examiner
Art Unit 1744

WHB